

Notice of Allowability

Application No.

10/521,367

Examiner

GiGi Huang

Applicant(s)

BAKHIT ET AL.

Art Unit

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to examiner's amendment requested on 4/12/2007.
2. ☒ The allowed claim(s) is/are 1-11,23,24 and 28.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 6/20/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

GiGi Huang
Patent examiner
Art unit 1609

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Brent Johnson on 4/12/07.

2. The application has been amended as follows:

a. Rewrite the claim 1 as following:

---- 1. (Currently amended) A dosage form comprising a prostamide and a trefoil factor family peptide wherein the prostamide is bimatoprost and the peptide is selected from the group consisting of TFF1 and TFF3. ----

b. In claim 2, line 2; delete [prostaglandin of] right before "prostamide".

c. Cancel claims 12-13, 22, and 25-27.

d. Cancel non-elected claims 14-21.

e. In claim 23, line 1, insert ----further---- right after "which".

f. Rewrite the claim 28 as following:

---- 28. (Currently amended) A pharmaceutical composition for treatment of glaucoma comprising a composition comprising a therapeutically effective amount of prostamide and a therapeutically effective amount of trefoil factor family

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peptide wherein the prostamide is bimatoprost and the peptide is selected from the group consisting of TFF1 and TFF3. ----

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance. Tan et al. (2000, Prostanoids mediate...) teaches the combination of trefoil factor with carbacyclin (an analogue of prostaglandin I₂ and/or prostaglandin E₂) for reduction of cell injury to the gastrointestinal mucosa. However, it fails to teach the use of bimatoprost as part of a composition with the trefoil factor family peptide, nor for the use in glaucoma. Thus the claimed invention is novel and patentably distinct over the prior art of the record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee, and to avoid delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on the Statement of Reasons for Allowance".

Conclusion

4. All the pending claims 1-11, 23-24, and 28 are allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM EST.

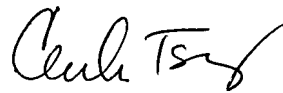
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562 or Vickie Kim (Primary

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Paten Examiner) at 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH



CECILIA TSANG
SUPERVISORY PATENT EXAMINER